APR - 8 2011

510K SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

The assigned 510(k) number is: K101745

Company/Contact person

Lisa Charter
Manager, Regulatory Affairs
Thermo Fisher Scientific, Clinical Diagnostic Division
46360 Fremont Blvd
Fremont, CA 94538
Phone: (510) 979-5142
Facsimile: (510) 979-5422
Email: Lisa.Charter@ThermoFisher.com

Date Prepared

February 14, 2011

Regulatory Declarations

Common / Usual Name	CEDIA® Amphetamine OFT Assay
Trade/ Proprietary Name	Thermo CEDIA® Amphetamine OFT Assay
Classification Regulation	21 CFR 862.3100
Device Class	Class II
Device Regulation Panel	Toxicology
Product Code	DKZ

Intended use

The CEDIA® Amphetamine OFT Assay is intended for use in the qualitative determination of amphetamine in human oral fluid at a cutoff concentration of 150 ng/mL in neat oral fluid. The specimen must be collected exclusively with the Oral-Eze™ Saliva Collection System. The assay is calibrated against *d*-amphetamine and performed on the MGC 240. This *in vitro* diagnostic device is intended for clinical laboratory use only.

The CEDIA Amphetamine OFT Assay provides only a preliminary analytical test result. A more specific alternative method must be used to obtain a confirmed analytical result. Gas Chromatography/Mass Spectrometry (GC/MS) and Liquid Chromatography-Tandem Mass Spectrometry (LC-MS/MS) are the preferred confirmatory methods. Clinical consideration and professional judgment should be applied to any drug of abuse test result particularly when preliminary positive results are used.

Conditions for use

The CEDIA® Amphetamine OFT Assay is for prescription professional use only in clinical chemistry laboratories. It is not for use in Point of Care settings.

Legally marketed device to which equivalency is claimed

CEDIA® Amphetamine OFT Assay is substantially equivalent to the previously cleared Immunalysis Amphetamine ELISA for Oral Fluids (K051579).

DESCRIPTION OF DEVICE

Principle of the CEDIA® Amphetamine OFT Assay

The CEDIA® Amphetamine OFT Assay uses recombinant DNA technology to produce a unique homogeneous enzyme immunoassay system. The assay is based on the bacterial enzyme β-galactosidase, which has been genetically engineered into two inactive fragments i.e., enzyme acceptor (EA) and enzyme donor (ED). These fragments spontaneously reassociate to form fully active enzyme that, in the assay format, cleaves a substrate, generating a color change that can be measured spectrophotometrically.

In the assay, analyte in the sample competes with analyte conjugated to one inactive fragment of β-galactosidase for antibody binding site. If analyte is present in the sample, it binds to antibody, leaving the inactive enzyme fragments free to form active enzyme. If analyte is not present in the sample, antibody binds to analyte conjugated on the inactive fragment, inhibiting the reassociation of inactive β-galactosidase fragments, and no active enzyme is formed. The amount of active enzyme formed and resultant absorbance change are directly proportional to the amount of drug present in the sample.

Principle of Oral-Eze™ Saliva Collection System

The Oral-Eze™ Saliva Collection System consists of Oral-Eze™ saliva collector and collection tube with preservative buffer. Oral-Eze™ saliva collector consists of an absorbent pad attached to a plastic handle. The saliva collector is provided with a volume adequacy indicator. The plastic handle has a round window where blue color will appear when sufficient volume of oral fluid is collected. Samples are collected by placing the collector pad and plastic shield between lower cheek and gum with the plastic shield facing the cheek. Oral fluid collection is done when blue color appears in the window of the handle. The pad is ejected in to the collection tube by placing thumb on the ridges on the handle and pushing the thumb forward. The collection tube is capped and sent to the laboratory for processing and testing.

Comparison of Technological Characteristics

CEDIA® Amphetamine OFT Assay is substantially equivalent to the previously cleared Immunalysis Amphetamine ELISA for Oral Fluids (K051579).

Comparison	Proposed Device CEDIA® Amphetamine OFT Assay	Predicate Device Immunalysis Amphetamine ELISA for Oral Fluids, K051579
Indications for Use	The CEDIA® Amphetamine OFT Assay is intended for use in the qualitative determination of amphetamine in human oral fluid at a cutoff concentration of 150 ng/mL in neat oral fluid. The specimen must be collected exclusively with the Oral-Eze™ Saliva Collection System. The assay is calibrated against *d*-amphetamine and performed on the MGC 240. This *in vitro* diagnostic device is intended for clinical laboratory use only. The CEDIA Amphetamine OFT Assay provides only a preliminary analytical test result. A more specific alternative method must be used to obtain a confirmed analytical result. Gas Chromatography/Mass Spectrometry (GC/MS) and Liquid Chromatography-Tandem Mass Spectrometry (LC-MS/MS) are the preferred confirmatory methods. Clinical consideration and professional judgment should be applied to any drug of abuse test result particularly when preliminary positive results are used.	The Immunalysis Amphetamine ELISA test system utilizes an Enzyme Linked Immunoassay (ELISA) for the qualitative detection of Amphetamine in oral fluid samples collected with the Quantisal™ oral fluid collection device using a cutoff of 50 ng/mL of d-Amphetamine. This in-vitro diagnostic device is intended for clinical laboratory use only. The Immunalysis Amphetamine ELISA Kit for Oral Fluids provides only a preliminary analytical rest result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical and Professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.
Test Principle	The CEDIA® Amphetamine OFT Assay uses recombinant DNA technology to produce a unique homogeneous enzyme immunoassay system. The assay is based on the bacterial enzyme β-galactosidase, which has been genetically engineered into two inactive fragments i.e., enzyme acceptor (EA) and enzyme donor (ED). These fragments spontaneously reassociate to form fully active enzyme that, in the assay format, cleaves a substrate,	Enzyme-labeled drug and drug present in the sample compete for limited antibody binding sites. Binding of the enzyme-labeled drug inhibits its reaction with the substrate, thereby influencing the rate of absorbance change measured by the instrument. The rate of absorbance change is proportional to the concentration of drug in the sample. Concentrations of controls and unknowns are calculated from the standard curve. Results are read at 450 and 620

	generating a color change that can be measured spectrophotometrically. In the assay, analyte in the sample competes with analyte conjugated to one inactive fragment of β-galactosidase for antibody binding site. If analyte is present in the sample, it binds to antibody, leaving the inactive enzyme fragments free to form active enzyme. If analyte is not present in the sample, antibody binds to analyte conjugated on the inactive fragment, inhibiting the reassociation of inactive β-galactosidase fragments, and no active enzyme is formed. The amount of active enzyme formed and resultant absorbance change are directly proportional to the amount of drug present in the sample.	nm.
Sample Matrix	Oral Fluid	Oral Fluid
Cutoff value	150 ng/mL in neat oral fluid	200 ng/ml in neat oral fluid 50 ng/ml diluted sample
Calibrator levels	0, 50, 200 ng/mL	50 ng/mL
Cutoff level	50 ng/mL	50 ng/mL
Unassayed Control levels	25, 75 ng/mL	25, 100 ng/mL

SUMMARY OF PERFORMANCE TESTING

Qualitative Precision

All samples tested recovered accurately. Samples at levels below the cutoff read as negative and samples at levels above the cutoff read as positive.

Qualitative Cutoff Characterization

All samples tested recovered accurately, low control as negative and high control level as positive.

Interference

Results demonstrated that there was no significant interference from endogenous and exogenous substances in oral fluid at the tested concentrations and in samples adjusted to pH range of 5 to 9.

Specificity and Cross-Reactivity

Cross-reactivity to metabolites and structurally related compounds was tested in the assay. No significant cross-reactivity was observed with other structurally unrelated compounds.

Amphetamine Method Comparison

The overall concordance between the CEDIA® Amphetamine OFT Assay and GC/MS is 100.0%. The comparison of sample results by the CEDIA® Amphetamine OFT Assay to GC/MS showed 100.0% sensitivity and 100.0% specificity.

Conclusion

As summarized, the CEDIA® Amphetamine OFT Assay is substantially equivalent to the Immunalysis Amphetamine ELISA for oral fluid. Substantial equivalence has been demonstrated through performance testing to verify that the device functions as intended and that design specifications have been satisfied.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Microgenics Corporation
c/o Lisa Charter
Manager, Regulatory Affairs
46360 Fremont Blvd.
Fremont, CA 94538

APR 0 8 2011

Re: k101745
Trade Name: Thermo Scientific CEDIA Amphetamine OFT Assay
Regulation Number: 21 CFR §862.3100
Regulation Name: Amphetamine test system
Regulatory Class: Class II
Product Code: DKZ
Dated: March 10, 2011
Received: March 14, 2011

Dear Ms. Charter:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Courtney Harper, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K101745

Device Name: Thermo Scientific CEDIA® Amphetamine OFT Assay

Indication for Use:

The CEDIA® Amphetamine OFT Assay is intended for use in the qualitative determination of amphetamine in human oral fluid at a cutoff concentration of 150 ng/mL in neat oral fluid. The specimen must be collected exclusively with the Oral-Eze™ Saliva Collection System. The assay is calibrated against *d*-amphetamine and performed on the MGC 240. This *in vitro* diagnostic device is intended for clinical laboratory use only.

The CEDIA Amphetamine OFT Assay provides only a preliminary analytical test result. A more specific alternative method must be used to obtain a confirmed analytical result. Gas Chromatography/Mass Spectrometry (GC/MS) and Liquid Chromatography-Tandem Mass Spectrometry (LC-MS/MS) are the preferred confirmatory methods. Clinical consideration and professional judgment should be applied to any drug of abuse test result particularly when preliminary positive results are used.

Prescription Use __X__ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Carol C. Benson

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K101745